

## **REMARKS**

Claims 1-49 are currently pending; claims 50-53 are withdrawn as being directed to a non-elected invention.

### **Rejection of Claims 19-32 Under § 112**

The Examiner has repeated his rejection of claims 19-32 under 35 U.S.C. § 112, second paragraph on the grounds that the use of the term “adapted and configured” renders the claims indefinite. The Examiner asserts that “[t]he term ‘adapted and configured’ in the claims is a relative term which renders the claim[s] indefinite.” The Examiner recites the following support for his position: (1) “The term ‘adapted and configured’ is not defined by the claim;” (2) the specification does not provide a standard for “ascertaining the requisite degree;” and (3) one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. (Office Action at p. 2).

First, as Applicant indicated in his previous response, there is no requirement in § 112 or the case law interpreting it that a claim contain a definition for any of its terms. The term “adapted and configured” can easily be understood by a skilled artisan.

The Examiner’s second point still makes no sense, and the Examiner’s word-for-word repetition of his rejection from the previous Office Action does nothing to clarify the point: Of what (or for what) must the specification provide the standard for ascertaining a requisite degree?

Finally, the Examiner has taken issue with Applicant’s assertion that a skilled artisan would understand the scope of each of claims 19-32 despite the use of the structural limitation “adapted and configured” in the claims. In particular, the Examiner complains that “Applicant has not set forth portions of the specification that define the various structure that would provide the function of the implant after removal or modification of some lamina or other portions of the vertebral bodies.” (Office Action at p. 3). The Examiner’s complaint is misplaced.

First, not every claim rejected here actually recites structure adapted to replace parts of the vertebral anatomy that have been removed or modified. For example, claim 19 recites structure adapted and configured to replace a natural articular process, but without stating that such structure had been previously removed.

Second, the specification describes the details of many embodiments (including the elected species) covered by these claims. For example, paragraph [0126] of the specification

describes the prosthesis 700 shown in Fig. 24 as being used in “hemiarthroplasty with wide decompressive laminectomy.” Figure 24 itself shows that portions of the vertebra are absent, such as after removal by such a procedure. The specification goes on to say that the prosthesis has at least one head member 710 (*i.e.*, the cephalad portion of a facet joint) articulating with a caudal portion of a facet joint (*e.g.*, a cup) to create a prosthetic facet joint capsule. (Spec. at ¶ [0128]). In fact, the specification has a very robust description of every species covered by these claims. The Examiner’s rejection of claims 19-32 under § 112 cannot be based on an insufficiency of Applicant’s disclosure.

While the Examiner may not like the term “adapted and configured,” there is no basis in the patent statute or case law for rejecting claims using that language. When read in light of the specification, the scope of each of claims 19-32 is clear. There is no need for these claims to specifically recite any more structure than each of them already does in order to meet the requirements of § 112. The Examiner’s rejection of claims 19-32 under § 112, second paragraph, is inappropriate and should be withdrawn.

#### Rejection of Claim 49 Under § 112

The Examiner rejected claim 49 under § 112, second paragraph, and suggested that the claim be reworded as a Markush group. Applicant has amended claim 49 as suggested by the Examiner. Claim 49, as amended, meets the definiteness requirements of § 112.

#### Rejection of Claims 13-15 Under § 101

On page 2 of the Office Action, the Examiner rejected claims 13-15 under 35 U.S.C. § 101 on the basis that the claims are directed to non-statutory subject matter because of their recitations of parts of the *in vivo* body structure as part of Applicant’s device. On page 4 of the Office Action, the Examiner repeated his § 101 rejection, but applied it only to claims 13 and 14. Applicant respectfully requests the Examiner to clarify the record on this point.

Claims 13-15 have been amended to address the § 101 rejection.

#### Rejection of Claims 1 and 33 Over Martin

The Examiner rejected claims 1 and 33 under 35 U.S.C. § 102(b) as being anticipated by Martin WO 95/05783 (“Martin”). The Examiner states that Martin discloses a device including

an “artificial joint structure” carried by a fastening element. (Office Action at p. 4). Claim 1 recites “an artificial left facet joint structure . . . adapted and configured to replace a cephalad portion of the left natural facet joint” and “an artificial right facet joint structure . . . adapted and configured to replace a cephalad portion of the right natural facet joint.” This rejection is identical to the rejection in the Office Action dated September 18, 2006. Applicant indicated in his response dated December 15, 2006, that the Examiner had not pointed to any part of Martin’s disclosure (which, except for the abstract, is in French) disclosing left or right artificial facet joint structures. The Examiner did not even attempt to rectify this omission in the most recent Office Action. In fact, Martin does not disclose such structure and therefore does not anticipate claims 1 or 33. This basis of the Examiner’s rejection is improper and should be withdrawn.

**Rejection of Claims 1-4, 12-18, 34-38 and 46-49 Over Zang, Wall, Homsy or Morgan  
Under § 102(b)**

The Examiner rejected claims 1-4, 12-18, 34-38 and 47-49 under 35 U.S.C. § 102(b) over any of Zang US 5,314,486 (“Zang”), Wall US 4,693,722 (“Wall”), Homsy US 4,778,472 (“Homsy”) or Morgan US 4,917,701 (“Morgan”). This rejection is identical to the rejection of these claims in the September 18, 2006 Office Action, including the Examiner’s omission of claim 46 when stating his rejection. (Applicant pointed this out to the Examiner in his last response, but the Examiner has not rectified the omission here.) Since the Examiner’s accompanying remarks make reference to claim 46, Applicant assumes the Examiner intended to include claim 46 in this listing of claims rejected under § 102(b) as well. Applicant respectfully requests the Examiner to clarify whether or not he intended to include claim 46 in his § 102(b) rejection over Zang, Wall, Homsy or Morgan so that the record will be clear for appeal.

As before, the Examiner contends that the prostheses disclosed by each of these references (1) “is structurally similar to that illustrated by applicant” and (2) “is capable of performing the function of replacing all or a portion of the natural facet joint.” (Office Action at pp. 4-5). The Examiner’s first point, however, misstates the requirements for anticipation. The question of anticipation under § 102 is not whether the reference discloses a device that is “structurally similar” to the device illustrated in Applicant’s figures but is rather whether the reference discloses each and every feature recited by the claims. As Applicant pointed out in his last response, the Examiner’s analysis does not even address the elements of claim 1.

As indicated before, the Examiner's second point is even more remarkable. Wall, Homsy and Morgan disclose temporomandibular joint prostheses. Zang discloses a metatarso-phalangeal joint prosthesis. The Examiner was not able to point to any disclosure in any of these references to support his contention that each of these prostheses could be implanted into a patient's spine to perform the function of replacing all or a portion of a natural facet joint.

Claim 1 recites a prosthesis with left and right prosthesis bodies accommodating fixation to a vertebral body at or near a pedicle and without support by a lamina. The Examiner's action does not explain how any of these references discloses these elements. Claim 1 further recites left and right artificial facet joint structures carried by the prosthesis bodies that are adapted and configured to replace cephalad portions of natural facet joints. None of these references discloses these elements either.

With respect to claims 2-4, the Examiner states that the claims are directed to a surgical step of attaching the assembly to the spinal structure. (Office Action at p. 6). In fact, however, these claims address how the prosthesis assembly's facet joint structures are fixed to the prosthesis assembly's prosthesis bodies. The Examiner has misread these claims. Applicant pointed this out in his last response, but the Examiner did not address this point in the most recent Office Action.

For at least these reasons, claims 1-4, 12-18, 34-38 and 46-49 are patentable over Zang, Wall, Homsy and Morgan under § 102 (b).

#### **Rejection of Claims 19-32 over Zang, Wall, Homsy or Morgan under § 102(b) or § 103(a)**

The Examiner rejected claims 19-32 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over any of Zang, Wall, Homsy or Morgan. The Examiner's remarks, however, appear to be directed to claims 2-17. In any event, the Examiner's argument is identical to the argument he used in support of the rejection of claims 19-32 under § 112(b): (1) "The term 'adapted and configured' is not defined by the claim;" (2) the specification does not provide a standard for "ascertaining the requisite degree;" and (3) one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. (Office Action at p. 7). As Applicant indicated in his prior response, the Examiner's argument does not even attempt to address the statutory requirements of §§ 102 or 103. Once again,

Applicant respectfully requests that the Examiner issue a new non-final office action identifying which claims he intended to reject and using the correct statutory basis for that rejection.

**Rejection of Claims 4-7 and 39-41 in view of Zang and Johnson**

The Examiner rejected claims 4-7 and 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Zang as applied to claim 1 and further in view of Johnson US 5,609,641 (“Johnson”). As discussed above, the Examiner never did apply Zang or any other reference specifically to claim 1. Nonetheless, Johnson fails to cure the deficiencies of Zang with respect to the elements of claim 1, from which each of these claims depend. Claim 1 recites a prosthesis with left and right prosthesis bodies accommodating fixation to a vertebral body at or near a pedicle and without support by a lamina and left and right artificial facet joint structures carried by the prosthesis bodies that are adapted and configured to replace cephalad portions of natural facet joints. Neither Zang nor Johnson, alone or in combination, discloses any of these elements. For at least these reasons, the Examiner’s rejection of claims 4-7 and 39-41 under § 103(a) over Zang and Johnson is improper and should be withdrawn.

**Rejection of Claims 8-11 and 42-45 in view of Zang and Carignan**

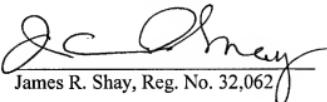
The Examiner rejected claims 8-11 and 42-45 under 35 U.S.C. § 103(a) as being unpatentable over Zang as applied to claim 1 and further in view of Carignan US 4,955,916 (“Carignan”). As discussed above, the Examiner never did apply Zang or any other reference specifically to claim 1. Nonetheless, Carignan fails to cure the deficiencies of Zang with respect to the elements of claim 1, from which each of these claims depend. Claim 1 recites a prosthesis with left and right prosthesis bodies accommodating fixation to a vertebral body at or near a pedicle and without support by a lamina and left and right artificial facet joint structures carried by the prosthesis bodies that are adapted and configured to replace cephalad portions of natural facet joints. Neither Zang nor Carignan, alone or in combination, discloses any of these elements. For at least these reasons, the Examiner’s rejection of claims 8-11 and 42-45 under § 103(a) over Zang and Carignan is improper and should be withdrawn.

### **CONCLUSION**

For the reasons stated above, claims 1-49 meet the requirements of §§ 101 and 112 and are patentable over the prior art of record under §§ 102 and 103. Applicant respectfully requests the Examiner to allow these claims and to pass this case to issue.

Respectfully submitted,

By:



James R. Shay, Reg. No. 32,062

Date: October 15, 2007

SHAY GLENN LLP  
2755 Campus Drive, Suite 210  
San Mateo, CA 94403  
Telephone: 650.212.1700  
Facsimile: 650.212.7562